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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,265	10/09/2001	Ashok Rampal	RLL-124CIPUS	8161

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RANBAXY INC.
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EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/973,265	Applicant(s) RAMPAL ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 8, 15, 16, 18-20 and 30-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-13, 21, 22 and 27 is/are rejected.
- 7) ☒ Claim(s) 4-7, 9, 14, 17, 23-26, 28 and 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' election of Group 1 is acknowledged. Group 1 includes claims 1-29, wherein composition must comprise both of the following: (a) a "neutral core" coated with a mixture of omeprazole and a pharmaceutically acceptable carrier and (b) one or more intermediate layers. Applicants have also responded to the "election of species" requirement by selecting the composition of Example 8, the contents of which is asserted to be disclosed in Tables 2 and 11.

Applicants have argued that claims 16 and 19 encompass the elected composition, because (a) the composition of example 8 is in the form of granules, and (b) granules are "comparable" to pellets. However, applicants are incorrect on the first point, and the wording of the second point is such as to be without impact. As stated on page 18, line 5 (specification), the composition of Example 8 is used to produce pellets that are filled into a capsule. As for granules being "comparable" to pellets, this term ("comparable") has no meaning with respect to either restriction, or 35 USC §103. The relevant term would be *obvious*. Applicants have stopped short of asserting that pellets are obvious over granules or *vice versa*. Accordingly, claims 16 and 19 are withdrawn from consideration.

Accordingly, claims 30-47 are withdrawn from consideration because they are not included within Group 1. Claims 8, 15, 16, 18-20 are withdrawn because they do not

encompass the elected composition. Claims 1-7, 9-14, 17, 21-29 are examined in this Office action.



Claims 10-13 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is dependent on itself.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 21, 22, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Lee (USP 6,228,400).

Lee discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer.

Thus, the claims are anticipated



Claims 1, 21, 22, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Bergstrand (WO 96/01623).

Bergstrand discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-insoluble polymer. Core materials are discussed at page 7, line 21+.

Thus, the claims are anticipated.



Claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by Lovgren (USP 4,786,505).

Lovgren discloses a composition comprising omeprazole and PVP.

Thus, the claims are anticipated.



Claims 1-3, 21, 22, 27 are rejected under 35 U.S.C. §102(e) as being anticipated by Henriksen (USP 6,391,342).

Henriksen discloses compositions in which a composition comprising omeprazole is coated

on a neutral core, and wherein the composition comprises a water-insoluble polymer which can be cross-linked PVP. (The PVP is referred to as a "disintegrant").

Thus, the claims are anticipated.



The following is a quotation of 35 U.S.C. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-3, 21, 22, 27 are rejected under 35 U.S.C. §103 as being unpatentable over Chen (USP 6,096,340).

Chen discloses compositions in which a composition comprising omeprazole is coated on a neutral core, and wherein the composition comprises a water-soluble polymer.

Chen does not disclose using cross-linked PVP. However, the use of cross-linked PVP is well known to drug formulation specialists who formulate omeprazole-containing compositions. The degree of cross linking affects the rate of dissolution. The drug formulation specialist of ordinary skill would have been motivated to use cross linked PVP to reduce the rate of dissolution.

Thus, the claims are rendered obvious.

*

- EP 0,519,365 was stricken from the IDS because of the absence of a translation. In addition, no English abstract has been received.
- JP 05-194225 was stricken from the IDS because of the absence of a translation. However, the abstract was considered.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON
PATENT EXAMINER
GROUP 1653